

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	
)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Magistrate Judge Marianne B. Bowler
<i>Inc., Zachary T. Bentley, and T. Mark Jones</i>)	
<i>v. Abbott Laboratories, Inc.,</i>)	
No. 07-CV-11618-PBS)	

**ABBOTT LABORATORIES INC.'S REQUEST FOR CERTIFICATION OF
INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(B)**

Pursuant to 28 U.S.C. § 1292(b), Abbott respectfully requests that the following questions be certified for an immediate interlocutory appeal to the First Circuit:

- Whether the United States, as plaintiff bringing claims under the False Claims Act and common law fraud, should be permitted to withhold, without *in camera* review, responsive documents under the deliberative process privilege which likely contain evidence centrally relevant to the defense of the action simply because the documents withheld do not specifically reference Abbott or the particular products named in the United States' complaint?
- Whether the United States waived its right to assert the deliberative process privilege in this case by failing to assert the privilege in the appropriate manner?

The Court's November 9, 2007 and March 12, 2008 rulings on the deliberative process privilege decided issues of central importance to this case, and implicate controlling questions of law.

Abbott respectfully suggests that there is substantial ground for difference of opinion on the approach taken by the Court, and that an immediate appeal will materially advance the ultimate resolution of this case and similar matters currently pending before this Court.

PRELIMINARY STATEMENT

At bottom, the United States seeks in this case to recover the full extent of the "spread," or "margin," between the Medicare and Medicaid payments it made for four families of Abbott

generic drugs (the “Subject Drugs”), allegedly influenced by reported drug prices, and the market prices of those drugs. The “spreads” were not, as plaintiffs declare, “mega-spreads” in any fair sense of the term.¹ Rather, the spreads on many if not most of Subject Drugs—primarily inexpensive commodity products like saline and dextrose solutions—are under \$10 per dose.

Abbott has made this Court aware of public documents and deposition testimony that leave no doubt that state and federal officials knew that the Medicare and Medicaid were paying a “margin” to providers on drug ingredient payments. (*See, e.g.*, Dkt. No. 5051, at 9-12, 14 n.9; Dkt. No. 5115 at 10-13.) These materials also show that the Government programs deliberately allowed an “appropriate margin” for a variety of policy reasons—to compensate for inadequate dispensing fees, encourage generic use, and ensure access to care.² There is every reason to believe that these policies were particularly apt for the types of infusion and injectable drugs at issue here, where the dispensing and administration fees paid by Medicare and Medicaid were well below the cost incurred in providing these drugs to beneficiaries.³ Indeed, even within the last year, CMS’s response to a recent OIG report *admits* that it is “pleased” that pharmacy

¹ The Government itself has acknowledged that the magnitude of spreads should be viewed in dollar terms, not through misleading percentages, on inexpensive generic drugs. *See* CONGRESSIONAL BUDGET OFFICE, MEDICAID’S REIMBURSEMENTS TO PHARMACIES FOR PRESCRIPTION DRUGS 3 (Dec. 2004) (Ex. A) (“the dollar markup is a better indicator of the size or adequacy of Medicaid’s reimbursements to pharmacies than is the percentage margin”). Relevant state and federal officials have indicated the same. Wiberg Dep. Tr. at 357:14-15 (Cody Wiberg, Pharmacy Program Manager for Minnesota Medicaid, 1999-2005: “[P]eople don’t spend percentages. They spend dollars.”) (Ex. B); Sullivan Dep. Tr. at 327:15-328:8 (Leo Sullivan, Director of Pharmacy Services for Tennessee Medicaid, 1989-2004: “the dollar difference is something that needs to be looked at first, because, you know, a thousand percent makes headlines but doesn’t mean anything if you don’t have a dollar amount affixed to it”) (Ex. C); Duzor Dep. Tr. at 487:6-488:8 (Dierdre Duzor, co-leader of CMS Medicaid Pharmacy Team: “if you have a prescription that’s a dollar and you have a hundred percent markup, that’s only another dollar”) (Ex. D).

² *See, e.g.*, GENERAL ACCOUNTING OFFICE, OUTPATIENT DRUG COSTS AND REIMBURSEMENTS FOR SELECTED PHARMACIES IN ILLINOIS AND MARYLAND 6 (Mar. 1993) (Ex. I to Dkt. No. 5051) (“Neither HCFA nor the states have determined what would be an appropriate margin between reimbursements and costs.”).

³ *See* Dkt. No. 5115, at 3-4 & n.1. Indeed, Robert Vito, an OIG official extensively involved in investigating AWP issues, testified that he has had conversations with HCFA officials regarding how the margin made by providers on drugs was being used to subsidize service costs. *See* Vito Dep. at 652:12-21, 654:2-15 (excerpts attached as Ex. 2 to Dkt. No. 5115). But before Abbott could learn more about those discussions, the Government shut down the questioning by asserting the deliberative process privilege. *See id.* The Government’s instructions are the subject of a separate motion to compel. *See* Dkt. No. 5112, Dkt. No. 5115.

providers under Medicare Part D are being paid \$9 “margins” on generic drugs for these very reasons. (*See* Ex. E at App’x G).

Because the Government policies reflected in these materials cover a broad range of drugs, these documents often do not specifically refer to “Abbott” or the Subject Drugs. But no one could in good faith contend that such materials are “irrelevant” or in any way “collateral” to a fraud case *that seeks to recover the very same margins* that these materials suggest were knowingly and deliberately paid by the Medicare and Medicaid programs. Quite to the contrary, such materials—regardless of whether they happen to mention “Abbott” or the “Subject Drugs”—are potentially dispositive of plaintiffs’ claims at summary judgment.

That is why, of course, the Government has fought tooth and nail to keep any additional damaging admissions under wraps through its overly broad assertion of the deliberative process privilege. Unfortunately, the Court’s resolution of the parties’ dispute on the deliberative process privilege—permitting the Government to withhold without *in camera* review any document unless it “relate[s] to its knowledge of a ‘spread’ for Abbott’s drugs at issue in this litigation or its knowledge of Abbott’s ‘marketing the spread’ for any its drugs”—has allowed the Government to do just that.

BACKGROUND

After extensive briefing by the parties on the applicability and scope of the deliberative process privilege, the Court ruled on November 9, 2007 that the Government must produce for *in camera* inspection only those documents “which relate to its knowledge of a ‘spread’ for Abbott’s drugs at issue in this litigation or its knowledge of Abbott’s ‘marketing the spread’ for any of its drugs.” *See* Order Re: Objections to August 13, 2007 Order by Magistrate Judge Bowler at 1 (Nov. 9, 2007) (Ex. F). The parties subsequently disagreed on the proper interpretation of the Court’s November 9, 2007 Order. Abbott understood the Order to require

review of documents that not only mentioned Abbott or Subject Drugs, but also those documents referring to classes of drugs (*e.g.*, generic drugs, infusion or injectible drugs) that necessarily “relate to” the Subject Drugs—so-called “cross-cutting evidence.” *See* Dkt. No. 5051, at 7-14.⁴ The Government, on the other hand, claimed that it was required to produce for *in camera* inspection only those documents that specifically reference Abbott or the Subject Drugs by name. Briefing on this issue ensued.

On February 1, 2008, Magistrate Judge Bowler ruled that the Government’s interpretation of the November 9, 2007 Order was correct; she also ruled that the Government did not have to search for or produce any additional documents from CMS’s Rulemaking Support Files and Office of Legislation. Abbott filed objections to both of these rulings. On March 12, 2008, apparently without having reviewed any documents on the Government’s privilege log, the Court issued a three-sentence docket entry to cover both issues:

The government shall review all its files (including the Office of Legislation and Rulemaking Support Files) for documents relating to Abbott’s marketing the spread or the the [*sic*] drugs at issue in this litigation. If there is a claim of privilege, the document shall be reviewed by the Magistrate Judge. Otherwise, the objections are denied.

Electronic Endorsement re: Mem. in Response to Abbott's Objs. to Magistrate Judge Bowler’s 2/1/08 Orders (March 12, 2008) (Ex. G). The Court’s March 12, 2008 ruling did not specifically address the parties’ disagreement as to the intended scope of the Court’s use of the term “relate to” in its November 9, 2007 Order. As a result, the Government has continued to bury all deliberative process documents that do not specifically mention Abbott or the Subject Drugs—regardless of their potential relevance to Abbott’s defenses.

⁴ Abbott contended that the Court, or a special master, should at least review a sample of withheld documents. *See* Dkt. No. 5051, at 6. Abbott proposed a sample for that review as Ex. 6 to Dkt. No. 5051.

ARGUMENT

Pursuant to 28 U.S.C. § 1292(b), a district court may certify an order for an immediate interlocutory appeal when the order:

- involves a “controlling question of law,”
- for which “there is substantial ground for difference of opinion,” and
- “an immediate appeal from the order may materially advance the ultimate termination of the litigation.”

See also In re Pharm. Indus. Average Wholesale Price Litig., No. 05-11084-PBS, 2008 WL 163644, at *1 (D. Mass. Jan. 16, 2008). The Court’s November 9, 2007 and March 12, 2008 Orders should be certified for immediate interlocutory review because (1) they involve a controlling issue of law, namely, the applicability and scope of the deliberative process privilege to potentially exculpatory documents in a case in which the Government is plaintiff, (2) there is substantial ground for difference of opinion on the resolution of those issues here, and (3) an immediate appeal would materially advance the ultimate resolution of this case (and others proceedings in the MDL) inasmuch as an immediate reversal would eliminate the need to belatedly re-open discovery and retry numerous complex cases more than once.

I. THE APPLICABILITY AND SCOPE OF THE DELIBERATIVE PROCESS PRIVILEGE HERE ARE CONTROLLING ISSUES OF LAW, RESOLUTION OF WHICH WILL MATERIALLY ADVANCE THE RESOLUTION OF THIS AND OTHER AWP LITIGATION.

The Court’s rulings on the applicability and scope of the deliberative process privilege implicate controlling issues of law suited for interlocutory appeal. A controlling question of law is one that is “serious to the conduct of the litigation, either practically or legally.” *See Johnson v. Burken*, 930 F.2d 1202, 1206 (7th Cir. 1991) (quoting *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974)); *see also In re Lupron Mktg. & Sales Practices Litig.*, 313 F. Supp. 2d 8, 9 (D. Mass. 2004) (finding that the court’s determination that TAP had waived

attorney-client privilege and work product protection involved a controlling issue of law, but denying certification on other grounds).

Abbott recognizes the general reluctance of courts to certify discovery orders for interlocutory appeal. However, in circumstances where an important discovery order will have significant practical importance to the advancement of the case and related proceedings, courts have found it appropriate to certify the question for appeal. For example, in *Baxter Travenol Laboratories, Inc. v. LeMay*, 514 F. Supp. 1156 (S.D. Ohio 1981), the defendants sought certification of the court's decision to uphold the plaintiffs' privilege objections blocking certain discovery. The Court recognized that "if [its] decision not to compel disclosure is erroneous, a retrial of the counterclaims (and perhaps, Plaintiffs' claims) might be avoided by an immediate appeal which corrects such error." *Id.* at 1158. The court also noted that the question to be certified "might have an impact on a large number of cases involving the . . . privilege." *Id.* at 1159. Considering the totality of the circumstances, including "the extent to which additional time and expense may be saved by avoiding a retrial," the court certified an appeal of the privilege issue under § 1292(b).

The court in *Flood v. Waste Management, Inc.*, No. 87 C 4643, 1989 WL 106689 (N.D. Ill. Sept. 14, 1989), faced a similar set of circumstances when it was asked to certify for appeal its decision denying defendants motion to compel allegedly privileged documents. Noting, "[c]learly, it is in no one's interest to try the case twice," the court certified the question for appeal. *Id.* at *2; *see also Garner v. Wolfenbarger*, 430 F.2d 1093, 1097 (5th Cir. 1970) (holding that an appeal regarding the "availability or unavailability of the testimony and documents sought" is available under § 1292(b) "where [the] decision on an issue would affect the scope of the evidence in a complex case, even short of requiring complete dismissal"); *Commonwealth*

Edison Co. v. Allis-Chalmers Mfg. Co., 225 F. Supp. 332, 338 (N.D. Ill. 1963) (certifying appeal of district court’s decision that interrogatories need not be answered because they sought irrelevant information where the issue “goes to the heart of these controversies”).

The practical considerations that influenced certification in these decisions are equally present here. The Court’s rulings have permitted the Government, the plaintiff here, to withhold over a thousand otherwise-relevant documents from Abbott pursuant to the Government’s broad assertion of the deliberative process privilege. Many of the withheld documents likely contain evidence that not only will show that the Government knew AWP greatly exceeded providers’ actual acquisition costs for drugs but, also, why the Government consciously decided to continue to use a payment methodology that it knew resulted in “overpayments” for prescription drugs. These documents will also likely contain information indicating that the Medicare and Medicaid programs deliberately maintained insufficient drug administration or dispensing fees levels *because of* the margin allowed on the drug ingredient side.

A few examples from the Government’s privilege log demonstrate the type of information that the Government is withholding under the Court’s rulings (emphases added):

- HHC902-00050016, described on the DOJ’s privilege log as a 1995 “draft proposal” described on DOJ’s privilege log as “*Discussion of alternative reimbursement mechanisms for the Medicare Program’s payment for drugs, and the pros and cons of such policies;*”
- HHC902-00590062, described as a “Draft NPRM . . . on drug and biological pricing policy. *Discusses potential affects of alternative reimbursement mechanisms;*”
- HHC902-02140244, a 1999 Memo with attachments described on DOJ’s privilege log as “Discussion of the issue regarding alternative reimbursement mechanisms and the use of DOJ data regarding one such alternative. *Presents an impact analysis of changes in reimbursement and its potential effect on the delivery of care, includes different documents, including a memo, handwritten notes, and charts.*”

The Court’s deliberative process privilege rulings shield these and hundreds of other potentially exculpatory documents from discovery—*critical documents that could substantially support a*

*summary judgment motion with respect to all or some of the Government's claims—*simply because they do not mention Abbott or the Subject Drugs by name.

The practical import of these rulings to this and other AWP litigation cannot be overstated. This is not a run-of-the-mill discovery dispute. Any suggestion otherwise would be patently disingenuous. Production of these documents would affect all aspects of this litigation going forward: summary judgment, settlement discussions, expert reports and discovery and, of course, trial. In the event that the Court's rulings are reversed, as Abbott contends they should be, numerous documents will likely be produced that will be important, if not indispensable, to the fact-finder at trial. It is unlikely that the Court's rulings allowing the Government to withhold documents that the Government has so desperately fought to protect would amount to harmless error. But if appellate review is delayed, this issue will hang over all future proceedings in the MDL—including the Government's claims against Dey and Roxanne—and could ultimately result in multiple lengthy and complex cases being retried across the country.

Moreover, the Court's rulings on the application of the deliberative process privilege in this case—a case in which the Government, as plaintiff in a fraud action, has placed its knowledge and deliberations at issue—raise important questions of law regarding the privilege's role in fraud litigation pursued by the Government. The Court's legal determination that the privilege shields all documents except those that specifically mention Abbott or the Subject Drugs places drastic limitations on Abbott's ability to defend itself. An immediate appeal of this issue will allow the First Circuit to settle the question of the privilege's applicability in this Government-initiated fraud case, and the extent to which the Government can raise the privilege to conceal highly relevant information.⁵

⁵ As Abbott has stated in its previous briefing, the Government has made no attempt to balance its need for protection under the deliberative process privilege with Abbott's right to discovery of documents relevant to its

II. **THERE ARE SUBSTANTIAL GROUNDS FOR DIFFERENCE OF OPINION ON THE APPLICABILITY AND SCOPE OF THE DELIBERATIVE PROCESS PRIVILEGE.**

The Court's deliberative process privilege rulings present substantial grounds for difference of opinion. By allowing the Government to conceal any document that does not happen to mention Abbott or the Subject Drugs—regardless of the substance of the document or its relevance to Abbott's defense—the Court's rulings conflict with decisions of other federal courts. Abbott believes the Court has misapplied the law, and that an immediate appeal would allow the First Circuit to fully review this Court's deliberative process privilege rulings prior to dispositive briefs being filed and considered and before lengthy and expensive trials take place.

A. **There Are Substantial Grounds For Difference Of Opinion Regarding The Propriety Of The Court's Approach To Resolving The Parties' Dispute Concerning The Deliberative Process Privilege.**

Because the Government must prove falsity, reliance, causation, and damages to prevail on its claims, the Government has necessarily placed its knowledge, deliberations, and actions at issue.⁶ Federal courts in similar cases have, therefore, severely restricted the Government's ability to withheld relevant, responsive documents under the qualified deliberative process privilege when it acts as the plaintiff in a lawsuit. *See Ghana Supply Comm'n v. New Eng.*

(continued...)

defense. Instead, the Government has asserted the privilege in the broadest possible manner. As a result, the Government has not released a single document to Abbott on the basis that its relevance outweighed the Government's privilege interests. Abbott believes this approach is irresponsible and contravenes basic principles of fairness in litigation.

⁶ *See, e.g., United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 445 (6th Cir. 2005) (if "plaintiff cannot show that the government agency would have acted differently had it known of the omission, 'there is no false claim because [the agency's action] would have occurred regardless of [the defendant's] actions'" (quoting *Rabushka ex rel. United States v. Crane Co.*, 122 F.3d 559, 563 (8th Cir. 1997))); *Teamsters Local 282 Pension Trust Fund v. Angelos*, 839 F.2d 366, 370 (7th Cir. 1988) ("In determining whether reliance was reasonable, all of the facts which plaintiff had actual knowledge of, as well as all of those it might have learned if it had used ordinary prudence, must be taken into account; if ample opportunity existed to discover the truth, then reliance is not justified."); *Francis v. Bankcard Am., Inc.*, No. 93 C 5510, 1999 WL 1289110, *8 (N.D. Ill. Jan. 4, 1999) ("The former inquiry into fraudulent intent focused on the defendants' actions. *This inquiry into justifiable reliance focuses on plaintiff's actions.*") (emphasis added).

Power Co., 83 F.R.D. 586, 593-94 (D. Mass. 1979) (“By far the great weight of authority holds that fairness to the defendant requires the government to make available all information relevant to the defense”) (collecting cases); *Dept of Econ. Dev. v. Arthur Andersen & Co.*, 139 F.R.D. 295, 299 (S.D.N.Y. 1991) (“Where the adjudication of fraud claims turns on issues of knowledge, reliance, and causation, direct evidence of the deliberative process is irreplaceable. . . . [A]t issue is the British Government’s knowledge of DeLorean’s activities, the extent of the knowledge, whether they justifiably relied upon AA’s reports or whether, as the defendants contend, the government chose to ignore certain information it had before it and nonetheless approve the grants for political issues.”).⁷

Even those courts that do not vitiate the privilege entirely when the Government acts as the plaintiff have applied the balancing test strictly against the Government.⁸ *See, e.g., United States v. Ernstoff*, 183 F.R.D. 148, 153 (D.N.J. 1998) (“courts have severely restricted the use of the privilege by government agencies that are seeking affirmative relief”); *Resolution Trust Corp. v. Diamond*, 773 F. Supp. 597, 605 n.7 (S.D.N.Y. 1991) (FTC’s role as plaintiff “tends to open

⁷ *See also Williams v. City of Boston*, 213 F.R.D. 99, 102 (D. Mass. 2003) (holding that when “the ‘decision-making process [of a government entity] itself is the subject of the litigation,’ it is inappropriate to allow the deliberative process privilege to preclude discovery of relevant information”) (quoting *Burka v. NYC Transit Auth.*, 110 F.R.D. 660, 667 (S.D.N.Y. 1986)); *Tri-State Hosp. Supply Corp. v. United States*, Civ. A. No. 00-1463, 2005 U.S. Dist. LEXIS 33156, *24-25 (D.D.C. Dec. 16, 2005) (“where the government’s intent is squarely at issue, there is no need for the court to engage in the tests applied in deliberative process privilege cases because ‘the privilege does not come into the picture.’”) (quoting *In re Subpoena Duces Tecum Served on the Comptroller of the Currency*, 145 F.3d 1422, 1425 (D.C. Cir. 1998)); *United States v. Lake County Bd. of Comm’rs*, 233 F.R.D. 523, 526 (N.D. Ind. 2005) (agreeing with decisions holding that the deliberative process privilege “is vitiated entirely at step one when the government’s decisionmaking process is central to the plaintiff’s case”); *Mitchell v. Fishbein*, 227 F.R.D. 239, 250 (S.D.N.Y. 2005) (“the deliberative process privilege is not applicable ‘[w]here the decision-making process itself is the subject of litigation’”) (citations omitted); *New York v. Oneida Indian Nation of New York*, No. 95-CV-0554, 2001 U.S. Dist. LEXIS 21616, *20 (N.D.N.Y. Nov. 9, 2001) (“If the party’s cause of action is directed at the government’s intent . . . and closely tied to the underlying litigation then the privilege cannot be permitted, and must ‘evaporate.’”) (internal citations omitted).

⁸ *In re Franklin Nat’l Bank Sec. Litig.*, 478 F.Supp 577, 583 (E.D.N.Y. 1979) (suggesting the following factors be balanced when considering whether deliberative process material should be produced: “(i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the ‘seriousness’ of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.”) (internal citations omitted).

the door to discovery of RTC's decision-making processes"); *United States v. Hooker Chems. & Plastics Corp.*, 123 F.R.D. 3, 12 (W.D.N.Y. 1988) ("Perhaps most importantly, the government asserting the privilege in this case is a party to the litigation."). As aptly stated by the court in the District of Maryland:

[W]hen the Government seeks affirmative relief, it is fundamentally unfair to allow it to evade discovery of materials that a private plaintiff would have to turn over, thus allowing the government to 'play with defendant's hole card upturned and its hole card down under any claim of governmental or executive privilege.'

EEOC v. Citizens Bank & Trust Co., 117 F.R.D. 366, 366 (D. Md. 1987) (quoting *EEOC v. Los Alamos Constructors, Inc.*, 382 F. Supp. 1373, 1383 (D.N.M. 1974)).

The Court's rulings in this case, which allow the Government to conceal any responsive deliberative process document that does not happen to specifically reference Abbott or the Subject Drugs, deviate substantially from this authority. In essence, the Court's rulings have subjugated three of the five factors in the balancing test—the relevance of the material, the availability of other evidence, and the harm caused by disclosure—to a novel formulaic test that depends on whether, by mere happenstance, a document (which may be critical in substance) mentions the right words. By way of example, neither the Government nor Abbott would expect that its lawyers' search for relevant documents in this case would amount to merely performing an electronic search for Abbott or the Subject Drugs.

Even the Government recognizes that its deliberations and policy decisions covered all drugs (or certain categories of drugs), and rarely mentioned specific drugs or drug manufacturers by name. *See* Jan. 31, 2008 Hr'g Tr. at 148:17-18 (Ex. H) ("[T]he policy of CMS [was] not established, was not developed by reference to Abbott's water product."). Abbott has shown the Court numerous examples of key documents found in the public record that are highly relevant

to its defense, yet do not happen to specifically reference Abbott or the Subject Drugs. *See, e.g.*, Dkt. No. 5051, at 9-12, 14 n.9; Dkt. No. 5115 at 10-13. Neither the Government nor the Court has explained how documents like these that are not publicly-available—documents that show the Government willingly paid margins for prescription drugs and thus was not defrauded into doing so—should not be produced in this case unless they happen to also mention Abbott or the Subject Drugs by name.

The flaws in the Court's approach are further magnified by the fact that no *in camera* review was conducted to ensure that the interests of the Government and Abbott were fairly balanced.⁹ Despite Abbott's request that the Court at least sample some of the documents from the Government's privilege log prior to making its ruling, and despite the Government's insistence that the Court should assess the merits of the Government's privilege assertions on a "document-by-document basis," it appears that the Court issued its ruling without doing so. As a result, the Government's privilege assertions have gone completely unchecked. For this reason, as well, there are substantial grounds for difference of opinion regarding the propriety of the Court's rulings on the deliberative process privilege.

B. There Are Substantial Grounds For Disagreement With The Court's Implicit Ruling On The Government's Waiver Of the Deliberative Process Privilege.

There are also substantial grounds for a difference of opinion concerning the Court's apparent ruling that the Government did not waive the deliberative process privilege by failing to

⁹ *See Kerr v. U.S. Dist. Ct. for N. Dist. of Cal.*, 426 U.S. 394, 405 (1976) ("In light of the potential seriousness of these considerations and in light of the fact that the weight to be accorded them *will inevitably vary with the nature of the specific documents in question*, it would seem that an *in camera* review of the documents is a relatively costless and eminently worthwhile method to insure that the balance between petitioners' claims of irrelevance and privilege and plaintiffs' asserted need for the documents is correctly struck.") (emphasis added); *Scott Paper Co. v. United States*, 943 F. Supp. 489, 498 n.8 (E.D. Pa. 1996) (noting the deliberative process privilege "usually requires examination of the documents *in camera*"); *In re Sealed Case*, 121 F.3d 729, 737 (D.C. Cir. 1997) ("[E]ach time [the deliberative process privilege] is asserted the district court must undertake a fresh balancing of the competing interests.") (internal quotation marks and citations omitted).

properly assert the privilege in this case. Although the Court has not explicitly addressed this issue in its rulings, it has upheld the Government's privilege assertions for nearly all of the documents withheld, even though the Government supported its privilege assertions with only vague statements contained in after-the-fact, lawyer-drafted declarations that simply tracked the general rationale for the deliberative process privilege and failed to articulate any concrete harm that would be occasioned by disclosure of the documents. *See* Dkt. No. 3960, at 10-13; Dkt. No. 4474, at 15-17 (recounting the Government's failure to assert the privilege appropriately).

Substantial authority calls into question this Court's implicit ruling that there was no waiver of the privilege. For instance, other courts have taken issue with assertions of the privilege that were similarly vague,¹⁰ lawyer-driven,¹¹ belated,¹² or bare of any articulation of concrete harm that would occur in the event of disclosure.¹³ *See Pacific Gas & Elec. Co. v. United States*, 70 Fed. Cl. 128, 136-37 (Fed. Cl. 2006) (ruling that because of the government's

¹⁰ *See, e.g., Resolution Trust Corp. v. Diamond*, 773 F. Supp. 597, 604 (S.D.N.Y. 1991) (rejecting assertion of deliberative process privilege when Government's affidavits provide "merely a paraphrase of the rationale for the deliberative-process privilege described in the case law").

¹¹ *See, e.g., Grossman v. Schwarz*, 125 F.R.D. 376, 381 (S.D.N.Y. 1989) ("Assertion of privilege by the attorney for the [government agency] or by the author of the document is insufficient.").

¹² *See, e.g., Anderson v. Marion County Sheriff's Dep't*, 220 F.R.D. 555, 562 n.5 (S.D. Ind. 2004) ("[T]he time to make the showing that certain information is privileged is at the time the privilege is asserted, not months later when the matter is before the Court on a motion to compel."); *Kelly v. City of San Jose*, 114 F.R.D. 653, 669 (N.D. Cal. 1987) ("To properly support each such objection the party also must submit, at the time it files and serves its response to the discovery request, a declaration or affidavit, under oath and penalty of perjury, from a responsible official within the agency who has personal knowledge of the principal matters to be attested to in the affidavit or declaration.").

¹³ *See, e.g., Pacific Gas & Elec. Co. v. United States*, 71 Fed. Cl. 205, 209 (Fed. Cl. 2006) (holding that the government's "vague, general and conclusory statement[s] as to why the confidentiality of the listed documents should be maintained" were insufficient, and ruling that the deliberative process privilege could be invoked "only if the proponent of the privilege explains *with particularity* how or why disclosures of the substance of the documents would harm an identified deliberative function.") (emphasis in original; internal quotation marks omitted); *Haus v. City of New York*, No. 03-4915, 2004 WL 3019762, at *4 (S.D.N.Y. Dec. 29, 2004) (ruling that the government's "formulaic assertion, taken almost word-for-word from innumerable other such agency submissions, plainly fails to offer a persuasive basis for believing that production under the governing confidentiality order would pose any harm to the public interest."); *Walsky Constr. Co. v. United States*, 20 Cl. Ct. 317, 320 (1990) (government must "supply the court with 'precise and certain reasons' for maintaining the confidentiality of the requested document") (citation omitted).

procedural failures in invoking the deliberative process privilege—invocation by the inappropriate official, no precise harm articulated, and belated assertion—the court “need not decide whether these documents meet the legal standards of the privilege by being ‘pre-decisional’ and ‘deliberative,’” or “‘balance the competing interests of the parties.’”) (internal citations omitted). Interlocutory review of this ruling is warranted because it will settle this decisive issue for this case and provide useful guidance to other similar cases that the Government is prosecuting. *See Marriot Int’l Resorts, L.P. v. United States*, 122 F. App’x 490, 491 (Fed. Cir. 2005) (certifying appeal from the trial court’s ruling that the deliberative process privilege did not apply because it was not asserted appropriately; accepting the United States’ assertion “that, although disposition of the issue would not dispose of the litigation, a court may grant a petition for permission to appeal if, e.g., review of the issue might simplify the litigation or affect other cases with similar important issues.”).

CONCLUSION

The Court’s November 9, 2007 and March 12, 2008 Orders on the applicability and scope of the deliberative process privilege decided questions that meet the criteria for immediate interlocutory appeal under § 1292(b). Abbott therefore respectfully requests the Court certify for appeal the following two questions:

- Whether the United States, as plaintiff bringing claims under the False Claims Act and common law fraud, should be permitted to withhold, without *in camera* review, responsive documents under the deliberative process privilege which likely contain evidence centrally relevant to the defense of the action simply because the documents withheld do not specifically reference Abbott or the particular products named in the United States’ complaint?
- Whether the United States waived its right to assert the deliberative process privilege in this case by failing to assert the privilege in the appropriate manner?

Dated: April 25, 2008

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES' REQUEST FOR CERTIFICATION OF INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(B) to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 25th day of April 2008.

/s/ David S Torborg